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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/768,442

01/24/2001

Chun-Ying Huang

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08/24/2006

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/768,442

Applicant(s)

HUANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 6/2/06 wherein claims 1-8 and 10 are canceled and claim 9 is amended.

Note: Claims 9 and 11 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 6/2/06 to the rejection of claims 9 and 11 made by the Examiner under 35 USC 102 103 have been fully considered and deemed persuasive-in-part for reasons of record in the office action mailed 12/30/05 and those set forth below.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

103 Rejection

I. The rejection of claims 9 and 11 under 35 USC 103(a) as being unpatentable over D'Amato (US Patent No. 5,629,327) and Masiero (Angiogenesis, 1997, Vol. 1, No. 1, pages 23-25) and Patierno (US Patent No. 5,696,092) is MAINTAINED for reasons of record in the office action mailed 12/30/05 and those set forth below.

In summary, Applicant makes the following assertions. Applicant asserts that the primary reference does not disclose any examples of solid tumors and that there is no specific disclosure concerning the use of thalidomide to treat hepatocellular carcinoma

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in the citation. In regards to Masiero et al, Applicant asserts that the citation does not suggest or imply the treatment of hepatocellular carcinoma by 30 to 1200mg of thalidomide as set forth in the instant invention. In regards to Patierno, Applicant asserts that the reference does not provide any hint concerning the treatment of hepatocellular carcinoma by using thalidomide in the specific amount set forth by Applicant.

First, Applicant is reminded that the rejection was made in combination; thus, attacking each reference individually does not overcome the cited prior art combination rejection. Secondly, in regards to D'Amato not providing examples of thalidomide to treat hepatocellular carcinoma, it should be noted that references are considered for their broad teachings and not limited to the teachings of a preferred embodiment. Thus, D'Amato was cited because the reference generally discloses treating solid tumors that are associated with angiogenesis using thalidomide. Also, D'Amato was cited because it discloses that thalidomide may be used to treat various cancers that have angiogenic behavior (e.g., that thalidomide is an anti-angiogenesis agent). As a result of the teachings of D'Amato, Masiero, and Patierno were cited because Masiero discloses that thalidomide is used to treat prostate and breast cancer and Patierno discloses that liver cancers are specifically treatable with anti-angiogenesis agents and that such cancers respond in a similar fashion to that of prostate cancer. Hence, a skilled practitioner in the art would be motivated to combine the teachings of Masiero and Patierno with the teachings of D'Amato. Furthermore, it is noted that D'Amato discloses that the thalidomide may be administered alone or in combination with some other component

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(column 4, lines 63-67). In regards to the dosage amount administered to a subject, D'Amato discloses that the dosage of the compound will depend on the condition being treated, the particular compound, and other clinical factors such as weight and condition of the subject and the route of administration of the compound (column 13, lines 7-16). In addition, in Example III (column 16), D'Amato disclose the used of thalidomide which is administered to a subject in an amount of 200 mg/kg for the particular condition being treated. Furthermore, a skilled practitioner in the art would be motivated to optimize the dosage amount administered to a subject based on the particular condition of interest and various dosages known in the art for treating other similar/related conditions using thalidomide.

II. The 103(a) rejection over Aarestrup et al is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a):

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

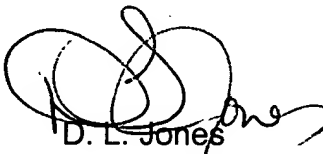
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

August 18, 2006